

REMARKS

The Office Action mailed July 27, 2007 was reviewed and the comments of the Patent and Trademark Office were considered. Claims 1 – 24 were pending in the application. Claims 1 – 10, 12 – 22 and 24 have been amended by this response, and claims 11 and 23 were cancelled. Therefore, claims 1 – 10, 12 – 22 and 24 are pending in the application and submitted for reconsideration. Support for these claims can be found throughout the claims originally filed and specification, for example paragraph [108-118].

This amendment adds, changes or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, are presented, with an appropriate defined status identifier. Applicant further reserves the right to pursue any cancelled claims in related applications.

Applicant's representatives ("Applicant") also thanks the Examiner for acknowledging that certified copies of the priority documents have been received and for accepting the drawings filed April 19, 2007.

Applicant also thanks the Examiner for the in person interview on December 5, 2007 to discuss the Ishibashi reference and how it does not apply to the instant claims.

PRIORITY

As noted by the Examiner in the Office Action, a Petition to Accept an Unintentionally Delayed Claim under 35 U.S.C. 120 was dismissed. As Applicant stated in the December 5, 2007 interview, a Petition to Accept an Unintentionally Delayed Claim was filed herewith on January 28, 2008, and should correct the priority, setting the priority date for the instant application to be October 9, 2001.

DOUBLE PATENTING REJECTIONS

The Examiner has provisionally rejected claims 1, 14, 15, 20 and 21 under 35 U.S.C. 101 as allegedly claiming the same invention of claims 1, 5, 6, 11 and 12 of copending Application No. 10/492,129. Applicant has amended the instant claims and the claims of Application No. 10/492,129. Applicant therefore requests that the Examiner withdraw this rejection. At the very

Application No.: 10/826,690

Response to Office Action issued July 27, 2007

Response dated January 28, 2008

least, the Applicant respectfully requests this rejection be held in abeyance until the indication of allowable subject matter.

The Examiner has also rejected claims 1 – 24 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 14 of U.S. Application No. 10/492,129. Applicant again respectfully requests this rejection be held in abeyance until the indication of allowable subject matter.

§ 101 REJECTION

The Examiner has rejected claim 23 under 35 U.S.C. 101 because the claimed invention is allegedly not supported by either a specific or substantial asserted utility or a well established utility. Although the Applicant strongly disagrees with the Examiner, by this amendment, claim 23 is cancelled. As such, Applicant respectfully requests the rejection be withdrawn.

§ 112 REJECTION

The Examiner has rejected claim 23 under 35 U.S.C. 112, first paragraph, alleging that the claimed invention is not supported by a specific and substantial asserted utility or a well established utility. Applicant respectfully disagrees, but by this amendment claim 23 is cancelled. As such, Applicant requests the Examiner withdraw the rejection.

The Examiner has rejected claim 11 and 12 under 35 U.S.C. 112, second paragraph, alleging that the claims are indefinite for failing to point out and distinctly claim the subject matter because they contain trademarks and trade names. Applicant respectfully notes that under MPEP 608.01(v) “[n]ames used in trade are permissible in patent applications if: (A) Their meanings are established by an accompanying definition... , or (B) In this country, their meanings are well-known and satisfactorily defined in the literature.” The names of the claims trademarks and trade names are proper because their meanings are well-known and defined in the literature. Applicant includes at Exhibit A evidence that the claimed trademarks and tradenames are well-known and defined in the literature, and therefore respectfully requests that this rejection be withdrawn. Applicant also reserves the right to supplement the evidence.

The Examiner also rejected claim 23 under 35 U.S.C. 112, second paragraph, alleging that the claim is indefinite for failing to point out and distinctly claim the subject matter. Although the

Application No.: 10/826,690

Response to Office Action issued July 27, 2007

Response dated January 28, 2008

Applicant strongly disagrees with the Examiner, by this amendment, claim 23 is cancelled. As such,

Applicant respectfully requests the rejection be withdrawn.

§ 102 REJECTION UNDER LEGRAND

The Examiner rejected claims 1 – 24 under 35 U.S.C. 102 (b) as being anticipated by Legrand (FR 2,830,447, published April 11, 2003). As Applicant stated in the December 5, 2007 interview, a Petition to Accept an Unintentionally Delayed Claim was filed on January 28, 2008 and should correct the priority, setting the priority date for the instant application to be October 9, 2001. As such, this rejection is obviated and Applicant respectfully requests the rejection be withdrawn.

§ 102 REJECTION UNDER ISHIBASHI

The Examiner rejected claims 1 – 24 under 35 U.S.C. 102 (b) as being anticipated by Ishibashi et al. (EP 1 101 490) (“Ishibashi”). Applicant respectfully traverses this rejection.

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegall Bros. V. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). *Ishibashi*, however, does not describe each and every element of the claims.

Independent claim 1 requires at least a microparticulate oral pharmaceutical dosage form for the delayed and controlled release of at least one AP, excluding perindopril, wherein the AP release is essentially limited to the upper parts of the gastrointestinal tract and occurs by a first triggering mechanism based on a variation in pH and a second triggering mechanism based on the residence time in the stomach, where at a constant pH of 1.4 the dissolution profile includes a latency phase with a duration less than or equal to 5 hours, and when pH changes from pH 1.4 to pH 6.8, there is a release phase that starts without a latency period.

Examiner alleges on pages 9 – 10 of the Office Action that in *Ishibashi* “it is required not releasing the medicinal substance for at least 2 hours in the second fluid (pH 6.8) of the disintegration test.” Thus, the Examiner states, *Ishibashi* and the instant invention “inherently have the same dissolution profile.” Office Action at 10. Applicant respectfully disagrees.

Independent claim 1 currently requires that at pH 6.8 there is release without a latency period. This feature is neither taught nor suggested by *Ishibashi*. Indeed, *Ishibashi* itself states that

for its preparations it “is required not releasing the medicinal substance for at least two hours ... [at] (pH 6.8)...” See, Ishibashi at ¶ 32. Indeed, Ishibashi teaches away from the instant claims.

Ishibashi clearly states that when “the medicinal substance is released rapidly at the upper small intestine, almost [sic] of the medicinal substance is wasted by absorption or decomposition...” See, Id. at ¶ 5. Thus, Ishibashi teaches that release in the upper parts of the gastrointestinal tract, which is where the pH changes from 1.4 to pH 6.8, leads to a waste of the composition. As such, Ishibashi teaches that their compositions avoid this waste by giving a latency of at least 2 hours at pH 6.8, and therefore teach away from the instant claims. In addition, the experiments of Ishibashi all show that in a pH 6.8 fluid, there is a latency period of over two hours for medicinal release. See, Figures 1, 2, 4 and 6. In contrast, the instant independent claim 1 requires that at pH 6.8 there is a release phase “without a latency period.”

Furthermore, the preparations of Ishibashi are designed to release at the large intestines or, at best, the lower parts of the intestine. As stated in Ishibashi itself, residence time in the stomach, where the pH is 1.8 to 4.5, can be from 0.5 to 10 hours. The residence time of a substance in the intestines, where the pH is 6.5 to 7.5, is only 3 ± 1 hour. As such, once the Ishibashi preparations move into the higher pH intestines, the preparations would not release the drug for at least another two hours. Thus, Ishibashi is aimed at a medicinal substance absorbed in the lower parts of the intestines and gives no guidance on how to achieve- or even if it possible to achieve- release without a latency period using the compositions of the Applicant's invention. In contrast, the preparations of independent claim 1 requires that the absorption of the AP is “essentially limited to the upper parts of the gastrointestinal tract.” Ishibashi does not teach or anticipate, inter alia, this element of the claim.

Finally, the instant claims are to use of a dual release triggering system, wherein the AP release occurs by a first triggering mechanism based on a variation in pH and a second triggering mechanism based on time. Ishibashi, however, does not teach or anticipate a dual triggering mechanism. Indeed, Ishibashi requires that no medicinal substance is released for at least 2 hours in the second fluid (pH = 6.8).

Further, the Examiner has alleged that Ishibashi teaches some of the hydrophobic organic compounds and enteric compounds used in the Applicant's hydrophilic polymer A and compound B. Office Action at 8. Applicant submits that the Examiner is picking and choosing from different portions of Ishibashi and adding the Examiner's own hindsight, which does not constitute anticipation, nor does it in any way demonstrate each element of the instant claims.

Even if the claimed subject matter could be divined from Ishibashi, it is well established that picking and choosing from different portions of a reference does not constitute anticipation. See, *In re Arkley*, 455 F.2d 586, 587 (CCPA 1972) (reversing the Examiner's 35 U.S.C. §102 rejection because the single Flynn reference did not clearly and unequivocally disclose the invention "without any need for picking, choosing, and combining" various portions of the reference that were directly related to each other) (emphasis in original); see also, *In re Wiggins*, 488 F.2d 538, 543 (CCPA 1973) (reversing the Examiner's 35 U.S.C. §102 rejection because the compounds, though named in the asserted reference, were not actually prepared).

The instant specification and claims are to a limited number of compounds for use in microparticulate oral pharmaceutical dosage form, which results in the dosage form having two triggering mechanisms, a dissolution profile with a latency phase less than or equal to 5 hours at a constant pH of 1.4, and a release phase that starts without a latency period when the pH changes from 1.4 to pH 6.8. The instant specification also explains how to use the composition to form compounds with the desired properties: properties completely counter to those taught by Ishibashi. Ishibashi, in contrast to the Applicant's invention, has a laundry list of at least 17 hydrophobic organic compounds and at least 45 enteric compounds. See, Ishibashi at ¶ 13. Applicant submits that although these compounds are named in the reference, there is no evidence that the compounds were actually prepared and have the properties of the instantly claimed dosage forms. The picking and choosing from the laundry list of compounds by the Examiner does not constitute anticipation.

In conclusion, Ishibashi does not anticipate independent claim 1 or any of their dependent claims because it does not anticipate each and every element as set forth in the claims. For example, Ishibashi does not teach release at pH 6.8 without a latency period, does not teach release essentially limited to the upper intestines and does not teach a dual release triggering system. Further, Ishibashi does not anticipate the instant claims or any of their dependent claims because the picking and choosing of compounds from Ishibashi, with use of hindsight, does not constitute anticipation. As claims 2 – 13, 15 – 17, 19 – 23 contain the limitations from independent claim 1, Ishibashi cannot anticipate the dependent claims. Thus, the Applicant respectfully requests the Examiner withdraw the 102 rejection.

Application No.: 10/826,690
Response to Office Action issued July 27, 2007
Response dated January 28, 2008


CONCLUSION

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), Applicant hereby petition for three months extension of time for filing a reply to the Office Action and submit the required \$1,050.00 extension fee herewith. The Director is hereby authorized to charge any deficiency in fees filed, asserted to be filed, or which should be filed (or any paper filed herewith in this application by this firm) to our Deposit Account No. 50-2228, under Order No. 022290.0116C1US from which the undersigned is authorized to draw.

In view of the foregoing, it is respectfully submitted that the pending claims are in condition for allowance. Entry of this amendment and an early notice to this effect is earnestly solicited. Should there be any questions regarding this application, the Examiner is invited to contact the undersigned at the number shown below.

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Respectfully submitted,

By 

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